Received: 22 February 2019 | Revised: 23 May 2019 | Accepted: 27 May 2019
DOI: 10.1002/joa3.12211

CASE REPORT

Journal of Arrhythmia Open Access WILEY

Troubleshooting in PM Leadless: How to manage an indissoluble knot

Giovanni Morani MD[1] | Bruna Bolzan MD[1] | Luca Tomasi MD[1] | Emma Zimelli MD[1] | Paola Marini MD[2] | Flavio Luciano Ribichini MD[1]

[1]Division of Cardiology, Department of Medicine, University of Verona, Verona, Italy
[2]Division of Pharmacology, Azienda Ospedaliera Integrata Verona, Verona, Italy

Correspondence
Giovanni Morani, Division of Cardiology, Department of Medicine, University of Verona, P.le A. Stefani 1, 37126 Verona, Italy.
Email: giovanni.morani@aovr.veneto.it

Abstract

A 77-year-old patient, with permanent atrial fibrillation, underwent successful Micra transcatheter pacing system (MTPS) implantation. Once begun the pull-back of the tether, an increasing resistance was felt by the operator until complete blockage. A challenging recapture of MTPS into the delivery system was performed. The retrieved MTPS showed an indissoluble knot close to the docking button that blocked the running of the tether, and a long clot inside the delivery system. The new design of internal handle components of MTPS recently updated seems to favor clot formation. We suggest a reconsideration of the standard recommendations about delivery system flushing and design of the inner flushing tube system.

KEYWORDS
leadless pacemaker, micra, micra implantation, micra transcatheter pacing system, MTPS retrieval

1 | INTRODUCTION

Micra transcatheter pacing system (MTPS) is an emerging technology successfully validated in clinical trials and post-approval registry.[1–3] However, along the growing experience, unexpected pitfalls may come up resulting in a major challenge for the operator.

2 | CASE REPORT

A 77-year-old patient, with permanent atrial fibrillation, diabetes mellitus, and chronic renal disease, underwent MTPS implantation by the means of the standard and recommended technique. Once advanced the delivery system and reached the proper position, MTPS was successfully implanted in the midseptum at the first deployment. Optimal electrical parameters (0.88 V at 0.24 ms pacing threshold, 12 mV sensing, 680 Ohm impedance) and tug test confirmed the successful implantation. Once the pull-back of the tether to release MTPS begun, an increasing step-by-step resistance was felt by the operator until to complete blockage, despite successful testing of both sides of the tether before cutting and an ongoing heparinized saline at 400ml/h flow rate. A challenging recapture of MTPS into the delivery system was performed with a strong traction along the single tether (Video S1). A new MTPS was successfully implanted. Examining the retrieved MTPS, we observed a surprising indissoluble knot (Figure 1; Video S2) close to the docking button that blocked the running of the tether, and a long clot inside the delivery system.

3 | DISCUSSION

Clot formation at the tip of Micra as well as inside the delivery system is not a new finding despite infusion of heparinized solution

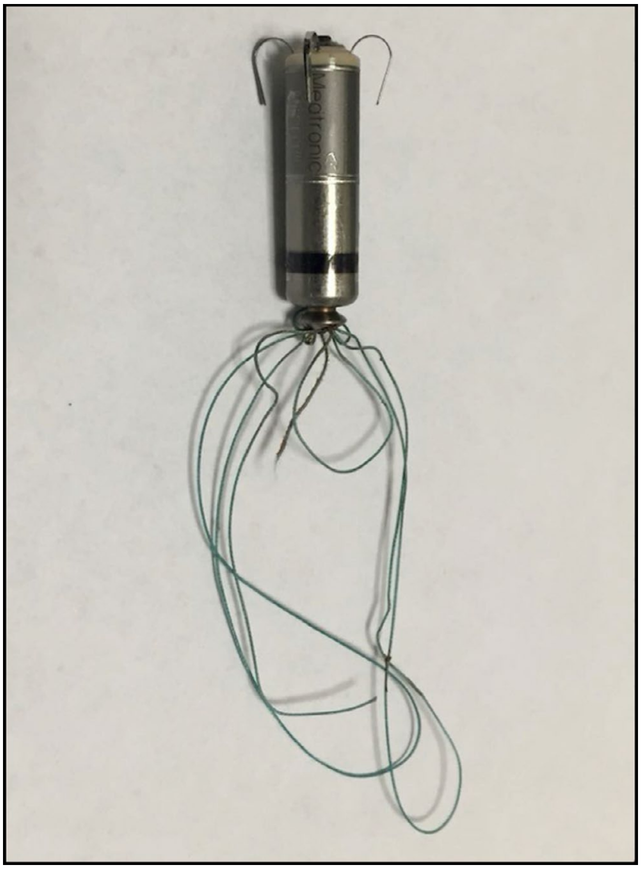

FIGURE 1 Micra knot close to the docking button

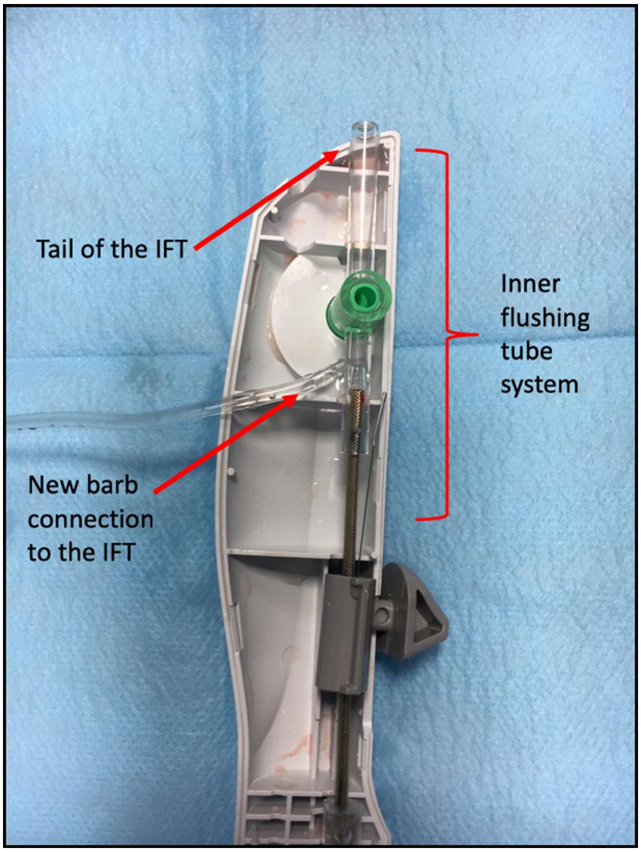

FIGURE 2 Section of MTPS handle showing the design of the inner flushing tube system

through the flushing port. Moreover, clot formation inside the delivery system has recently been reported in association with a case of indissoluble knot formation. Adequate heparinized saline flow rate was recommended by the authors.[4,5] In our case, high flow rate of heparinized saline did not prevent knot and clot formation.

Observing the section of the handle, we can notice that flushing the system through the flush port, after tether pin removal, results in large flushing of the tail of the inner flushing tube but the antegrade flow along the main body of the delivery is absent (Figure 2; Video S3). According to the physics of fluids, the resistance to flow increases as the length of tube increases and decreases as the radius increases. The tail of the inner flushing tube connecting to the tether pin is shorter and larger than the long inner flushing tube of the delivery. A fluid under pressure always takes the path with least resistance. Once removed the tether pin, increasing the heparinized saline flow rate through the flushing port results in heparinized saline dispersion through the tail. In addition, the flushing port connection to the inner flushing tube is through a newly designed barb addressing the fluid toward the tail. Conversely, by occluding the tail of the inner flushing tube with a finger, we obtain an adequate antegrade flow that, in our following experience, seems to be effective to prevent or reduce clot formation inside delivery system. Even if the mechanism of the knot is unknown, preventing clot formation may facilitate proper running of the tether inside the delivery system and the docking button.

After the experience reported, we performed MTPS implantation by changing our technique and we did not have encountered any problems. Now for every procedure, after Micra deployment, just after cutting the tether we close the inner flushing tube with a finger to favor the antegrade flow along the main body of the delivery and we flush the system under pressure through the port access by using a syringe with heparinized saline. Since august 2018, we have adopted this technique resulting in faster tether retrieval, without clot formation and without knot formation.

A recent technological update of the internal structure of the delivery system has been introduced (Figure 2), with a new inner assembly and a new design of internal handle components. The inner lumens changed from 4 lumens to 3 lumens with lumen common to flush and tether (Video S4), and the lumen material changed from PTFE to PFA. Whether this change is involved in the mechanism of knot formation is still unknown, but the knot formation is a recent finding.

We suggest reconsideration of the standard recommendations about delivery system flushing and to evaluate technological improvement of the inner flushing tube system.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

ORCID

Giovanni Morani https://orcid.org/0000-0003-3538-4051

REFERENCES

1. Reynolds D, Duray GZ, Omar R, Soejima K, Neuzil P, Zhang S, et al; Transcatheter Pacing Study Group. A leadless intracardiac transcateter pacing system. N Engl J Med. 2016;374(6):533–41.
2. Duray GZ, Ritter P, El-Chami M, Narasimhan C, Omar R, Tolosana JM, et al; Micra Transcatheter Pacing Study Group. Long-term performance of Transcatheter pacing system: 12-months results from the Micra Transcatheter Pacing Study. Heart Rhythm. 2017;14(5):702–9.
3. El-Chami MF, Al-Samadi F, Clementy N, Garweg C, Martinez-Sande JL, Piccini JP, et al. Updated performance of the Micra transcatheter pacemaker in the real-world setting: a comparison to the investigational study and a transvenous historical control. Heart Rhythm. 2018;15(12):1800–7.
4. Arias MA, Rubio MA, Miguel R, Pachón M. Thrombus formation at the tip of a leadless pacemaker causing multiple unnecessary repositioning. Heart Rhythm. 2016;13(11):2265.
5. Cipolletta L, Volpato G, Biffi M, Capucci A. An indissoluble knot: An unexpected troubleshooting during Micra implantation. Pacing Clin Electrophysiol. 2018 [Epub ahead of print].

SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of the article.

How to cite this article: Morani G, Bolzan B, Tomasi L, Zimelli E, Marini P, Ribichini FL. Troubleshooting in PM Leadless: How to manage an indissoluble knot. *J Arrhythmia*. 2019;35:676–678. https://doi.org/10.1002/joa3.12211